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| 10/724,680 | 12/01/2003 | Erning Xia | P03295 | 2368 |

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| EXAMINER | |
|---|---|
| HUYNH, CARLIC K | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/724,680 | XIA ET AL. | |
| | Examiner | Art Unit | |
| | Carlic K. Huynh | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,5,13-17 and 20-22* is/are pending in the application.

4a) Of the above claim(s) *5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,13-17 and 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 December 2003 and 6 May 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

1. Claims 1, 3, 5, 13-17, and 20-22 are pending in the application in response to the restriction requirement submitted on March 6, 2007. Accordingly, claims 1, 3, 5, 13-17, and 20-22 are being examined on the merits herein.

### *Election/Restrictions*

2. Applicant's election of the claims of Group I, namely claims 1-5, 13-17, and new claims 20-22, in the reply filed on April 26, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-12 and 18-19 are drawn to a nonelected invention and have been cancelled in a Preliminary Amendment filed on April 5, 2007.

3. Applicants' election of (1) polyquaternium-10 as a single disclosed species of a cationic polysaccharide and (2) polyquaternium-1 as a single disclosed species of an anti-microbial agent, in the reply filed on April 26, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 3, 13-17, and 20-22 are read to be drawn on polyquaternium-10 and polyquaternium-1.

Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made in the reply filed on April 26, 2007. Because Applicants did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1, 3, 13-17, and 20-22 are being examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Claims 1, 3, 13-17, and 20-22 are drawn to compositions and thus intended use is not give any patentable weight.

***Information Disclosure Statement***

The Information Disclosure Statements submitted on December 1, 2003 and May 6, 2005 are acknowledged.

***Specification***

4. The use of the trademarks Polymer JR 125™, Polymer JR 400 ™, Polymer JR 30M ™, Polymer LR 400 ™, Polymer LR 30M ™, Polymer LK ™, Pluronics ™, R-Pluronics ™, Tetronics ™, R-Tetronics ™ and Dequest® have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, 13-17, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richard et al. (US 5,858,937) in view of Hue et al. (US 6,274,133).

Richard et al. teach an aqueous solution comprising an antimicrobial agent, polyquaternium 1 (column 7, line 50). The aqueous solution also comprise a series of surfactants identified as the poloxamer series, which is a poly(oxyethylene) poly(oxypropylene) block polymers (column 6, lines 21-24). The aqueous solution further comprises buffers, tonicity agents, and hydroxypropyl cellulose as a viscosity agent (column 6, lines 46-50; column 7, lines 2-3; and column 7, line 29). The aqueous solution has a final osmotic value of 200 to 450 mOso/kg (column 7, lines 19-20). When used, the aqueous solution is in contact with the lens (abstract).

Richard et al. do not teach an aqueous solution comprising cationic polysaccharides of polyquaternium-10.

Hu et al. teach an ophthalmic solution containing a cationic cellulosic polymer that binds to extended wear contact lens and prevents the accumulation of lipids, proteins, and other products (abstract). Specifically, Hu et al. teach compositions comprising Polymer JR 30M (column 10, lines 39-40).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the aqueous solution of Richard et al. to contain Polymer JR 30M because the ophthalmic solution of Hu et al. contains Polymer JR 30M and according to Hu et al., Polymer JR 30M are cationic polysaccharides of polyquaternium-10 that bind to the contact lens and prevent the accumulation of lipids, proteins, and other products.

The motivation to combine the compounds of Hu et al. to the compounds of Richard et al. is that the compounds of Hu et al. are cationic polysaccharides of polyquaternium-10 that bind to the contact lens and prevent the accumulation of lipids, proteins, and other products.

***Double Patenting***

**Obviousness-Type**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 13, and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12 of McCanna et al. (US 6,153,568), claims 11 and 16 of Denick, Jr. et al. (US 6,348,508), and claims 1, 6-7, and 12 of Xia et al. (US 7,067,479) in view of Richard et al. (US 5,858,937).

Richard et al. teach antimicrobial agents are quaternary ammonium compounds, e.g. polyquaternium 1, and the biguanides (column 7, lines 39-40 and 50).

The conflicting claims are not identical but they are not patentably distinct. Claim 12 of McCanna et al. is directed at methods of using a polyquaternium polymer and a polymeric biguanide. Polyquaternium-10 of the instant claims 1 and 13 is a polyquaternium polymer and biguanide of the instant claims 1 and 13 is a polymeric biguanide. Claims 11 and 16 of Denick, Jr. et al. are directed at a method of using a solution comprising a cationic cellulosic polymer and biguanide. Polyquaternium-10 of the instant claims 1 and 13 is a cationic cellulosic polymer and biguanide is the same biguanide used in instant claims 1 and 13. Claims 1 and 6 of Xia et al. are directed at a method using a composition comprising polyquaternium-10 and biguanide, which is the same polyquaternium-10 and biguide used in the compound of instant claims 1 and 13. Thus the composition or solution comprising polyquaternium-10 and biguanide is not patentably distinct between McCanna et al., Denick, Jr. et al., Xia et al., and the instant application.

Claim 1 of McCanna et al. is directed at a solution comprising a polyquaternium polymer and a polymeric biguanide, which is not patentably distinct over the instant claims 1 and 13

because the cationic polysaccharide polyquaterium-10 is a polyquaternium polymer and the antimicrobial agent, biguanide, is a polymeric biguanide. Thus the composition comprising polyquaternium-10 and biguanide is not patentably distinct between McCanna et al. and the instant application.

7. Claims 1, 3, and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-6, 10, 13-14, 18-20, 22, 28-29, 33-35, 37, 44, 48-49, 51, 54-55, 60, 66-67, 71-72, 74, and 78 of copending Application Xia et al. (US 2005/0214382).

The conflicting claims are not identical but they are not patentably distinct. Claims 1, 5-6, 10, 13, 44, 48-49, 51, 54, 67, 71-72, 74, and 78 of Xia et al. are directed at a method or process of using a compound or solution comprising a cationic cellulosic polymer and an anti-infective. Polyquaternium-10 of the instant claims 1 and 13 is a cationic cellulosic polymer and an antimicrobial agent of the instant claims 1 and 13 is an anti-infective. Thus the composition or solution comprising polyquaternium-10 and an antimicrobial agent is not patentably distinct between Xia et al. and the instant application.

Claims 14, 18-20, 22, 28-29, 33-35, 37, 55, 60, and 66 of Xia et al. are directed at a composition comprising a cationic cellulosic polymer and an anti-infective, which is not patentably distinct over the instant claims 1 and 13 because the cationic polysaccharide polyquaterium-10 is a cationic cellulosic polymer and the antimicrobial agent is an anti-infective. Thus the composition comprising polyquaternium 10 and an antimicrobial agent is not patentably distinct between Xia et al. and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

8. Claims 1 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 20-21, 28-31, 47-48, 55-59, and 74-75 of copending Application Salamone et al. (US 2006/0047005), claims 1, 12-14, 17, and 20 of copending Application Borazjani et al. (US 2006/0205621), claims 1, 11-12, and 25-26 of copending Application Lever, Jr. et al (US 2006/0292105), claims 1, 3-5, 9, 11, 13-15, 19, 21, 23-25, and 29 of copending Application Borazjani et al. (11/611,328), and claims 1, 8-12, 14, 16, 20, 27-31, 33, 35 of copending Application Borazjani et al. (11/611,360) in view of Richard et al. (US 5,858,937).

Richard et al. teach antimicrobial agents are quaternary ammonium compounds, e.g. polyquaternium 1, and the biguanides (column 7, lines 39-40 and 50).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 28-31, and 47-48 of Salamone et al. are directed at a method of producing a composition or solution comprising polyquaternium-10 and polyquaternium-1, which is the same polyquaternium-10 and polyquaternium 1used in the instant claims 1 and 13. Thus a composition or solution comprising polyquaternium-10 and polyquaternium 1 is not patentably distinct between Salamone et al. and the instant application.

The conflicting claims are not identical but they are not patentably distinct. Claims 1, 12-14, 17, and 20 of Borazjani et al. (US 2006/0205621) are directed at methods of using a solution comprising cationic polysaccharide and biguanide. Polyquaternium 10 of the instant claims 1 and 13 is a cationic polysaccharide and an antimicrobial agent of the instant claims 1 and 13 is

biguanide. Claims 1, 3-5, 9, 11, 13-15, 19, 21, 23-25, and 29 of Borazjani et al. (11/611,328) are directed at a method of using a composition comprising a cationic polysaccharide and biguanide. Polyquaternium 10 of the instant claims 1 and 13 is a cationic polysaccharide and an antimicrobial agent of instant claims 1 and 13 is biguanide. Claims 1, 8-12, 14, 16, 20, 27-31, 33, and 35 of Borazjani et al. (10/611,360) are directed at a method of using a solution comprising a cationic polysaccharide and an antimicrobial agent. Polyquaternium 10 of the instant claims 1 and 13 is a cationic polysaccharide and polyquaternium 1 of instant claims 1 and 13 is an antimicrobial agent. Thus the composition or solution comprising polyquaternium 10 and an antimicrobial agent such as biguanide is not patentably distinct between Borazjani et al. (US 2006/0205621), Borazjani et al. (11/611,328), Borazjani et al. (10/611,360), and the instant application.

Claims 1-4, 20-21, 55-59, and 74-75 of Salamone et al. are directed at a composition or solution comprising a polyquaternium-10 and polyquaternium-1, which is not patentably distinct over the instant claims 1 and 13 because polyquaterium-10 is a polyquaternium-10 and polyquaternium-1 is a polyquaternium-1. Thus the composition or solution comprising polyquaternium-10 and polyquaternium-1 is not patentably distinct between Salamone et al. and the instant application.

Claims 1, 11-12, and 25-26 of Lever, Jr. et al. are directed at a composition or solution comprising a polyquaternium-10 and a biguanide, which is not patentably distinct over the instant claims 1 and 13 because polyquaterium-10 is a polyquaternium-10 and poly(hexamethylene biguanide is a biguanide. Thus the composition or solution comprising

polyquaternium-10 and a biguanide is not patentably distinct between Lever, Jr. et al. and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

***Conclusion***

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

SHENGJUN WANG
PRIMARY EXAMINER